Biomix Network Limited	PAGE NO : 1 OF 24
RECORD	BATCH NO. :
BATCH MANUFACTURING RECORD	BATCH SIZE : LITERS
PRODUCT : RECEPTOL ORAL SPRAY	MFG. DATE :
REC. NO. : REC-720-01	EXP. DATE :

SERIAL NO.:

RECEPTOL ORAL SPRAY

Proprietary Nutraceutical
(Prolin Rich Polypeptides Oral Spray))

BATCH NO	**:**	
MFG. DATE	**:**	
EXP. DATE	**:**	
BATCH SIZE	**:**	**Liters**

MANUFACTURED BY : BIOMIX NETWORK LTD.
NEAR KHATRAJ CROSS ROAD,
KHATRAJ, DIST – KHEDA , PIN – 387 130
GUJARAT, INDIA

LABLE CLAIM **:** Receptol is a pure natural product with active ingredients of Nano info Peptide of Prolin Rich Polypeptides (0.3 % of solids)derived from Bovine Lacteal Source by Nano biotechnology method.
INGREDIENTS:
Purified Water, Lactose, Prolin RichPolypeptides (0.3% of Solids) Flavoring substances Vanilla Flavor., Preservatives – Sodium Benzoate, Potassium Sorbate and Disodium EDTA

NUTRITIONAL FACTS:
Amount per 100 ml
Energy : 10 kcl
Protein : 0.3 g
Carbohydrates : 2.5 g

REV. NO. : 03

SHELF LIFE : 2 YEARS

MFG. LIC. NO. : AC/MDC/ND/3169

ISSUED BY :

DATE OF ISSUE :

Sign of Chemist	
Reviewed By -	Approved By -

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A. MASTER FORMULA

Sr. No.	Code No.	Ingredients	Unit Formula Mg / 3 ml	Batch Formula for 1000 lt. (In Kg.)	Batch formula for _____ lt. (In Kg.)
01		Colostrum Whey	2700	900	
02	RM-001/08	Sodium Benzoate	3.0	1.00	
03	RM 002/08	Potassium Sorbate	3.0	1.00	
04	RM-003/08	Di Sodium EDTA	3.0	1.00	
05	RM-005/08	Flavor Vanilla	1.5	0.500	
06		D.M Water for di filtration *	q.s	q.s	
07	RM-004/08	Citric Acid @	q.s	q.s	

* D.M.Water: Quantity of D.M.Water for di filtration will be up to make the volume as per batch size

@ Citric Acid Quantity of Citric Acid for ph adjustment up to 5.0

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B. PRECAUTIONS & INSTRUCTIONS

7

PRECAUTIONS:

01. Wear nose mask and hand gloves while handling product.
02. Avoid direct contacts & inhalation of active materials.

Instructions:

01. Raw material approved by Quality Control Department should only be used.
02. Store in air tight containers.
03. Label all the equipment and container to be used with suitable status label. Status label Should indicate Product, Batch No & Manufacturing Stage.
04. Check the equipment for cleanliness.
05. Check for line clearance.
06. Check the material dispensed as per formula sheet.
07. The temperature of the area should be 20 to 25˚C.

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C. DISPENSING SHEET

Sr. No.	Ingredients	Qty	Quantity		Control No.	Weighed By	Checked By	Date
			Assigned	Consumed				
01	Colostrum Whey	Kg						
02	Sodium Benzoate	Kg						
03	Potassium Sorbet	Kg						
04	Di Sodium EDTA	Kg						
05	Flavor Vanilla	Kg						
06	D.M Water for di filtration *	Kg						
07	Citric Acid for ph adjustment @	kg						

* D.M.Water: Quantity of D.M.Water for di filtration will be up to make the volume as per batch size

@ Citric Acid Quantity of Citric Acid for ph adjustment up to 5.0

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D. EQUIPMENT CLEANING PROCEDURE

BULK CHILLER – 1

1. Close out let valve of Bulk Chiller – 1 & switch off cooling system & agitator.
2. Connect Bulk Chiller – 1 out let with inlet line of Whey Receiving System.
3. Ensure out let of Whey Receiving line connects to Bulk Chiller – 1 as on inlet.

A) HOT WATER CLEANING (Frequency – Daily)

1. Fill approx. 100 lts. of Hot water laving temp. 75 – 80 ^{O}C by means of steam operated mixer.
2. Open outlet valve of Bulk Chiller – 1 & start pump of Prefiltration unit & circulate hot Water through whey inlet line & filter housing assembly for 30 min.
3. Drain water by connecting outlet of Bulk Chiller – 1 to drain line.

B) ALKALI CLEANING (Frequency – Daily)

1. Prepare 0.1N NaOH Solution (400 gm of NaOH in 100 lts. of Water) & follow Hot Water Cleaning Procedure.

C) ACID CLEANING (Frequency – Daily)

1. Prepare 0.2% Sodium Metabisulphate solution (200gm Sodium Metabisulphate in 100 lts. Of Water) & follow Hot Water Cleaning Procedure.

D) SANITIZATION

1. Prepare 40 PPM Sodium Hypo chloride Solution & follow Hot Water Cleaning Procedure.

E) FINAL HOT WATER

1. To remove of traces of sanitizing agent from the system finally clean the system with Hot water having temp. 75-80˚C & follow the Hot Water Cleaning Procedure.

F) Document all cleaning Procedure including temp &time in separate cleaning Record Sheet.

FILTER UNIT – 1

1 Open four clamps from the top of the unit

2 Open lid of filter unit & remove S.S. support plate from housing & kept it in specified container

3 Remove the 1.0 micron filter from the hosing & kept it in specified container, now carry that container at location where hot water and compressed air facilities provided

4 First Cleaned it with hot water till complete trances of product remove physically

5 Then Cleaned it with DM water & lastly blow compressed air to remove trances of product form holes

D. EQUIPMENT CLEANING PROCEDURE

(a) Clean clamp,S.S lid , S.S.bolt and rubber gasket first with hot water then with 1 % Iodofor solution and lastly with D.M. Water. Packed it in Cleaned poly bag along with gasket if not in use

b) Once in a week sanitize the filter with 40 ppm sodium hypo chloride solution followed by hot water, DM water & compressed air to remove the trances of sanitizer & packed it in Cleaned poly bag it not in use.

FILTER UNIT - 2

1 Open clamp from the top of a filter unit & kept it in specified container
2 Open lid of filter unit & kept it in specified container
3 Un screw all three filter bolt from the top & kept it in specified container
4 Remove 0.45 micron filter safely with rubber gasket one by one & kept it in specified container , now carry that container at location where hot water and compressed air facilities provided
5 First Cleaned it with hot water till complete trances of product remove physically
6 Then Cleaned it with DM water & lastly blow compressed air to remove trances of product from Holes
7 Clean clamp,S.S lid , S.S.bolt and rubber gasket first with hot water then with 1 % Iodofor solution and lastly with D.M. Water. Packed it in Cleaned poly bag along with gasket if not in use
8 Once in a week sanitize the filter with 40 ppm sodium hypo chloride solution followed by hot water, DM water & compressed air to remove the trances of sanitizer

PREFILTRATION UNIT

Filtration Rate : 0.3 Micron
Qty of Membrane : 03 Nos

A HOT WATER CLEANING (Frequency – Daily)
1. Connect CIP tank with Prefiltration system
2. Ensure direction of permeate line & Retentate line it should go back to CIP tank.
3. Fill CIP tank with water having temp. 50˚C & circulate it for 30 min. thought. Prefiltration system, without applying inlet pressure to system & finally drain out thought drain points.

B ALKALI CLEANING (Frequency – Daily)
1. Fill CIP tank with100 letters hot water
2. Make 0.1N NaOH Solution by adding (400 gm / 400 ml NaOH in 100 letters water) & circulate it for 30 min. thought Prefiltration system without applying inlet pressure to system & finally drain out solution thought drain point

C ACID CLENING
a ACID CLEANING (Frequency - Daily)

D. EQUIPMENT CLEANING PROCEDURE

1. Again fill CIP tank with 100 lts. Water.
2. Make 0.2% Sodium Metabisulphate Solution (by adding 200gm Sodium Metabisulphate in 100 lts. of water). Circulate it for 30 min through Prefiltration system, without applying inlet pressure to system & finally drain out solution through drain point.

b ACID CLEANING (Frequency - Weekly)

1. FOR REMOVEL OF DIRT
   - ❖ Prepare 0.1% HCL (V/V) solution & follow the hot Water Cleaning Procedure.
2. FOR REMOVEL SCALE

❖ Prepare 0.1% HCL (V/V) & 2% Citric Acid. Mixture in warm water (40-50^{O}C) and follow water Cleaning Procedure.

D SYSTEM SANITISATION (Frequency - Weekly)

1. Prepare 40 PPM solution of Sodium Hypochlorite in water & follow the Water Cleaning Procedure.

E To remove traces of cleaning agent do the daring of system with DM water & follow water cleaning procedure until pH water found 7.0

NOTE: STORAGE OF SYSTEM FOR NON OPERATING CONDITION

1. If system is to be kept ideal for more than 72 hrs. Then membrane must be soaked in 0.5% Sodium Metabisulphate solution.
2. Follow Water Cleaning Procedure.

F Document all cleaning Procedure including pressure & flow parameter in separate cleaning Record Sheet.

ULTRAFILTRATION STAGE – 1

Filtration Rate : 100 KD
Qty of Membrane : 05 Nos

A WATER CLEANING (Frequency – Daily)

1. First remove the solution laying in system thought 3 drain points located below the system & close the feed valve of system & Drain valve.
2. Fill DM water in balance tank – 1 up to 100 Lts.having temp.40˚C
3. Now open feed out let valve of tank, & air vent valve & initially close permeate valve.
4. Start pump adjust RPM of motor by rotating speed regulator in clock wise direction- initial, set 250 RPM & gradually increase up to 350 RPM.
5. Now open permeate valve & adjust pressure up to 0.2Kgs/CM2 to retentate valve & allow permeate to go in Ultrafiltration – 2
6. Continue cleaning for 30 min & record all parameters in separate cleaning record sheet

D. EQUIPMENT CLEANING PROCEDURE

7. Stop the m/c remove water from balance tank – 1. Through drain points located bellow the sys.

B ALKALI CLEANING (Frequency – Daily)

1. Prepare 0.1N NaOH solution (400 gms of NaOH in 100 Lts. Of DM Water) follow the Water Cleaning Procedure.

C SANITIZATION OF SYSTEM (Frequency – Weekly)

1. To minimize microbial load of membrane, sanitize the system once in a week.
2. Prepare 1 % Formaldehyde solution (1 Lts of Formaldehyde in 100 Lts. Of Water) & follow the water Cleaning Procedure.

D WATER CLEANING

1. To remove traces of cleaning agent.
2. Do the cleaning of system with DM Water & follow cleaning system procedure until pH of water found 7.0

E Document all cleaning Procedure including pressure & flow parameter in cleaning Record Sheet.

ULTRAFILTRATION STAGE – 2

Filtration Rate : 10 KD
Qty of Membrane : 05 Nos

A WATER CLEANING (Frequency – Daily)

1. First remove the solution laying in system through 3 drain points located below the system & close the feed valve of system & Drain valve.
2. Fill DM water in balance tank – 2 up to 100 Lts.
3. Now open feed out let valve of tank, & air vent valve & initially close permeate valve.
4. Start pump adjust RPM of motor by rotating speed regularator in clock wise direction- initial, set 250 RPM & gradually increase up to 350 RPM.
5. Now open permeate valve & adjust pressure up to 0.2Kgs/cm2 to retentate valve & allow permeate to go in Bulk Chiller – 2 Unit or recalculate it to Balance tank – 1.
6. Continue cleaning for 30 min & record all parameters in separate cleaning record sheet
7. Stop the m/c remove water from balance tank – 2. Through drain points located bellow the system.

B ALKALI CLEANING (Frequency – Daily)

1. Prepare 0.1N NaOH solution (400 gms of NaOH in 100 Lts. Of DM Water) follow the Water Cleaning Procedure.

D. EQUIPMENT CLEANING PROCEDURE

C SANITIZATION OF SYSTEM (Frequency – Weekly)

1. To minimize microbial load of membrane, sanities the system once in a week.
2. Prepare 1 % Formaldehyde solution (1 Lts of Formaldehyde in 100 Lts. Of Water) & follow the water Cleaning Procedure.

D WATER CLEANING

1. To remove traces of cleaning agent.
2. Do the cleaning of system with DM Water & follow cleaning system procedure until pH of water found 7.0

E Document all cleaning Procedure including pressure & flow parameter in cleaning Record Sheet.

BULK CHILLER – 2 & FILLING LINE

- ❖ Close outlet valve of bulk chiller – 2 & switch off cooling system & agitator.
- ❖ Ensure outlet line of Bulk Chiller – 2 are in circulation mode.
- ❖ Ensure outlet points of circulation line are connecting with Balk Chiller – 2.

A HOT WATER CLEANING (Frequency – Daily)

1. Fill approx 100 Lts. of Hot water having temp. 75 – 80^{O}C by means of steam operated mixture.
2. Open outlet valve of Bulk chiller – 2 & start pump from panel board in manual mode & circulate Hot Water through filling line for 30 minutes.
3. Drain water by connecting outlet of Bulk Chiller – 2 to drain line.

B ALKALI CLEANING (Frequency – Daily)

1. Prepare 0.1N NaOH solution (400 gms of NaOH in 100 Lts. Of DM Water) follow the Hot Water Cleaning Procedure.

C ACID CLIEING (Frequency – Daily)

1. Prepare 0.2% Sodium Metabisulphate solution (200gm in 100 Lts of water), & follow Hot water Procedure.

D SANITISATION

1. Prepare 40 ppm Sodium Hypo Chloride Solution & follow Hot Water Cleaning Procedure.

E FINAL HOT WATER CLEANING

1. To remove traces of cleaning / sanitizing agent from the system, finally clean the system with Hot Water having temp. 75 – 80^{O}C & follow the Hot water cleaning Procedure.

F Document all cleaning Procedure including temp &time in separate cleaning Record Sheet.

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E. MANUFACTURING PROCEDURE

RECEIVING OF WHEY

1 Whey is a starting material for our product, so we are considering it as a main raw material of our product.
2 Process of manufacturing of whey is carried out at Amul premises, we are receiving it as a raw material time to time, and in fact Amul is supplying it time to time up to our plant.
3 Before reaching whey to our Plant QC has to certify quality of whey, if parameter of whey found complies, then we will collect it in our plant as a raw material.
4 For receiving of whey starting operation of filter unit 1 & 2

FILTER UNIT - 1

- Unscrew clamp of filter unit
- Insert 1.0 micron filter along with s.s.screen and support plate
- Tighten the screw of filter unit

FILTER UNIT - 2

- Unscrew clamp of filter unit
- Insert 0.45 micron filter one by one and tightened the bolt accordingly
- Tighten the clamp of filter unit

5 For receiving release emergency of panel of whey transfer system then verify the three was valve position, it should remain on to receiving end.
6 Ensure housing of filter unit – 1 & filter Unit – 2 are filled with 1.0 micron filter & 0.45 micron filter respective.
7 Ensure that out let of whey receiving line are connected properly to Bulk Chiller – 1.
8 Press green colour push switch & start pump. Whey will start to come through 1.0 micron filter & 0.45 micron filter respectively in to Bulk Chiller-1.
9 Note down the reading of pressure gauges of Filter unit – 1 & filter Unit – 2 before, after & during receiving. in BMR
10 After completion of receiving process, note down level of whey through. Deep stick reading, from corresponding. Level Vs Qty. Chart and record it in BMR.
11 Switch on the mains of Bulk Chiller – 1 & start compressor (Colling system) as well as agitator simultaneously.
12 Note down temp. Reading from temp. Indicator initials & after every half an hours in BMR.
13 Temp. Indicator has already set programmed for temp. between (4 to 8^{O}C)

PREFILTRATION

A OPERATION
1. Open out let valve of Bulk Chiller – 1
2. Ensure valve position of permeate line to balance tank & Retentate line return to bulk chiller in forward position.

E. MANUFACTURING PROCEDURE

3. Rotate pressure regulator valve in anti clock wise direction up to last position (Ensure zero Pressure)
4. Keep regulator switch in auto mode so unit will start automatically
5. Adjust inlet pressure/ out let pressure through pressure regulating valve up to 3 kg/cm2 by rotating it clock wise direction.
6. Note down flow rate reading as well as inlet pressure/ out let pressure, & permeate pressure in BMR as per frequency mentioned.

B DI-FILTRATION

1. Extra DM Water Qty. (10% of total Batch size.) is to be added on line in feed through out filtration system to reduce the concentric of Retentate.
2. Ensure, D.M. Water pass through Microbiological Retentive Filter.
3. Ensure,,pH of D.M.Water, It should be within 6 to 8 and carried out Organoleptic taste and record the same dilfiltration record
4. Check the quality of filtered water with hygiene meter and record the same in difiltration record. The reading should not be more than 50
5. Out of 10% of DM Water qty. of total Batch size 8% of water qty. to be added on line in Bulk chiller – 1.
   1% of DM Water qty. of total Batch size. to be added on line in Balance Tank – 1.
   1% of DM Water qty. of total Batch size. to be added on line in Balance Tank - 2.
6. Note down time Vs Qty. added in respective record.

C FLUSH THE SYSTEM WITH WATER

1. After completion of operation connect CIP tank with Prefiltration unit.
2. Fill approx. 100lts. Of water in CIP tank & ensure direction of valve position of Retentate & permeate towards CIP tank.
3. Open all three drain point of system.
4. Start pump of CIP tank & circulate it through system for 20 min & remove all water of CIP tank in drain through drain point.
5. Repeat the same operation (Step 2 to 4) with Hot Water having temp. $50^{O}C$.

D SOAK THE MEMBRANES WITH ALKALI SOLUTION

1. Fill approx. 100 Lts. Of water in CIP tank & prepare 0.1N NaOH solution (400 gms in 100lts of water) heat it up to $50^{O}C$.
2. Close the drains have of system.
3. Start pump of CIP tank & circular it through system for 30 min. a leave the system as it is so membrane will remain soaked in ablative solution until next operation / cleaning.

ULTRAFILTRATION STAGE – 1

A OPERATION

1. Switch on the main supply of m/c from ultra filtration panel board.
2. Release emergency switch (if press). Immediately,
   "Power On"

E. MANUFACTURING PROCEDURE

"Drive Read"
"Control on" – Indicator glow.

3. Physically check feed level in balance tank, it should be up to lower level of sensor
4. Ensure a main valve of balance tank out let is on.
5. Be sure valve position of feed in to membrane 01, 02, 03, 04 & 05 is open.
6. Be sure valve position of feed out from membrane 01, 02, 03, 04 & 05 is open.
7. Be sure valve position of Retentate valve & permeate valve is open.
8. Initial keep air vent valve in open position & permeate valve in closed position. Ensure all drain point valve are closed
9. Now push pump on switch & rotate regulator located on panel board of clock wise direction & adjust desire speed of pump up to 350 RPM
10. Speed of pump in terms of RPM indicates on panel board.& Ensure that air bubbles are removing from air vent then close the air vent valve & open permeate valve, now apply pressure to retantate valve up to 0.2Kg/CM^2 & allow permeate to go to Balance tank-2.
11. Record all parameters in BMR. As per frequency decided like,
    - Pressure before strainer. (Pump out let)
    - Pressure after strainer. (Feed pressure)
    - Temp of feed.
    - Retented pressure.
    - Permeate pressure.
    - Flow rate of Permeate.

B DI-FILTRATION

As mentioned in Prefiltration Stage

C FLUSH THE SYSTEM WITH WATER.

1. After completion of operation, fill approx. 100 Lts. Of water in balance tank-1.
2. ensure valve position of permeate, retantate & air vent valve all should be open.
3. open all drain valve of system.
4. Now start pump from panel board & adjust 350 RPM for motor.
5. Empty out all liquid of Balance tank-1 & system thorough drain point.
6. Repeat the same operation (Stage No. 1 to 5) with Hot water laving temp. $40^{O}C$.

D SOAKING OF MEMBRANCE WITH ALKALI SOLUTION

1. Fill approx. 100 Lts. Of water in Balance tank-1 & prepaid 0.1 N NaOH solution (400 gms NaOH in 100 Lts. Of water) Heat it up $40^{O}C$.
2. Close all drain valve of system.
3. Close permeate valve & ensure retenate valve & air vent valve position, it should remain open.
4. Start the pump & circulate alkali solution thought system for 30 min. & leave the system as it is so all membrance win remain soaked with alkali solution, until next operation / Cleaning.

E. MANUFACTURING PROCEDURE

ULTRAFILTRATION STAGE – 2

A OPERATION

1. Switch on the main supply of m/c from ultra filtration panel board
2. Switch on the main supply of m/c from ultra filtration – 2 panel board.
3. Release emergency switch (if pressed). Immediately,
   "Power on"
   "Drive Ready"
   "Control on" - Indicated will glow.
4. Physically check feed level in balance tank, it should be up to lower level of sensor.
5. Turn on main valve of balance tank out let.
6. Be sure valve position of feed in to membrane 01, 02, 03, 04 & 05 is open.
7. Be sure valve position of feed out from membrane 01, 02, 03, 04 & 05 is open.
8. Be sure valve position of Retentate valve & permeate valve is open.
9. Initial kept air vent valve in open condition & permeate valve in closed position. Ensure air drain point valve is closed.
10. Now switch on pump & rotate regulator located on panel board to clock wise direction & adjust desire speed of pump up to 350 RPM.
11. Speed of pump in terms of RPM indicates on panel board. & ensure that air bubbles are removed through air vent & then close the air vent valve & open permeate valve, now apply pressure to retentate valve up to 0.2Kg/CM^2 & allow permeate to go to Bulk Chiller – 2.
12. Record all parameters in BMR. As per frequency decided
    - Pressure before stainer
    - Pressure after strainer
    - Temp. Of Feed.
    - Retentate pressure.
    - Permeate pressure.
    - Flow rate of Permeate.

B DI-FILTRATION

As mentioned in Prefiltration

C FLUSH THE SYSTEM WITH WATER.

1. After completion of operation, fill approx. 100 Lts. Of water in balance tank-2.
2. Ensure valve position of permeate, retentate & air vent valve all should be open.
3. Open all drain valve of system.
4. Now start pump from panel board & adjust 350 RPM for motor.
5. Empty out all liquid of Balance tank-1 & system thorough drain point.
6. Repeat the same operation (Stage No. 1 to 5) with Hot water laving temp. 40^{O}C.

D SOAKING OF MEMBRANCE WITH ALKALI SOLUTION

E. MANUFACTURING PROCEDURE

1. Fill approx. 100 Lts. Of water in Balance tank-1 & prepaid 0.1 N NaOH solution (400 gms NaOH in 100 Lts. Of water) Heat it up 40^{O}C.
2. Close all drain valve of system.
3. Close permeate valve & ensure retentate valve & air vent valve position, it should remain open.
4. Start the pump & circulate alkali solution thought system for 30 min. & leave the system as it is so all membrance win remain soaked with alkali solution, until next operation / Cleaning.

ADDITION OF PRESERVATIVES AND FLAVORS

1.0 take 10 lts of D.M water in suitable S.S. container

2.0 heat it up to 70 ˚ C add following preservatives with continuous stirring

Sr.No	Name of Preservatives	Quantity in Kgs
01	Sodium Benzoate	
02	Patasium Sorbate	

3.0 cool it up to normal temp at about 20˚ C and filter it through 200 # nylon muslin cloth

4.0 Add it drop by drop directly in to bulk chiller - 2

5.0 take another 10 Lts of D.M water in suitable S.S. container

6.0 heat it up to 70 ˚ C add following preservatives with continuous stirring

Sr.No	Name of Preservatives	Quantity in Kgs
03	Di Sodium EDTA	

7.0 cool it up to normal temp at about 20˚ C and filter it through 200 # nylon muslin cloth

8.0 Add it drop by drop directly in to bulk chiller - 2

9.0 Take 5.0 Lts of D.M. water in suitable S.S. container and add following flavor in it with Continuous stirring filter it thought 200 # nylon muslin cloth.

Sr.No	Name of Flavor	Quantity in Kgs
04	Vanilla extract	

5.0 Add this solution drop by drop in Bulk Chiller – 2 with continuous stirring

ADDITION OF CITRIC ACID

1.0 make 10.0 Lts of 20 % solution of Citric Acid in hot water and filters it through 200 # nylon muslin cloth

2.0 add above solution gradually with constant stirring up to 2..0 lts in to Bulk Chiller -2

3.0 then check the pH of solution lying in Bulk Chiller-2

4.0 addition of remaining solution with constant stirring until pH of solution found near to pH 5.0

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D. EQUIPMENT CLEANING RECORD

I. ENVIRONMENT CONDITION OF MFG. AREA

Sr. No.	Date	Time	Temperature ˚C.	Sign.

II. EQUIPMENT CLEANING

PREVIOUS PRODUCT: _____ **BATCH NO.: _____**

Equipments	Equipment No.	SOP NO.	Cleaning				
			From	To	Done by	Checked by/ Date	
						Prod	QA.
Filter - 1	B-PD-EQ-001/08	SOP-720-01					
Filter - 2	B-PD-EQ-002/08	SOP-720-01					
Bulk Chiller - 1	B-PD-EQ-003/08	SOP-720-01					
Pre-Filtration	B-PD-EQ-005/08	SOP-720-02					
Ultra Filtration (Stage – 1)	B-PD-EQ-007/08	SOP-720-03					
Ultra Filtration (Stage – 2)	B-PD-EQ-009/08	SOP-720-04					
Bulk Chiller -2	B-PD-EQ-010/08	SOP-720-05					

III. FILTER CLEANING RECORD

Date	Time	Filter Size	Filter Checked Before Use	Sign. Of Chemist		Filter Checked After Use	Checked by Chemist.
				PROD.	Q.A.		
		1.0 mic					
		0.45 mic					

IV. CLEANING OF MANUFATURING AREA.

Date	Started At	Completed At	Name of Operator	Sign of Chemist	Remarks

Sign of Chemist

Reviewed By -

Approved By -

D. EQUIPMENT CLEANING RECORD

V. CLEANING OF EQUIPMENT

S.No	Name of Equipment	Cleaning Details	Timing		Done By	Checked by
			From	To		
1	Prefiltration					
2	Ultrafiltration -1					
3	Ultrafiltration -2					

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E. MANUFACTURING RECORD

1) WHEY RECEIVING RECORD

A) Pressure Record

Sr. No	Date	Before Filter Unit 1			After Filter Unit 1			After Filter Unit -2		
		Before During	On During	After During	Before During	On During	After During	Before During	On During	After During

B) Bulk Chiller – 1 Qty. Record

Date	Time	Deep Stick Reading	Qty in Lts.	Done By.	Checked By.

C) Bulk Chiller – 1 Temp. Record.

Date	Time	Temp. ^{O}C	Done By	Checked By	Remarks

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F. MANUFACTURING RECORD

2) DIFILTRATION RECORD

A) D.M Water Quality Record (After passing through Filter)

S.No	Date	Taste	pH	Hygiene reading	Done By	Checked by

B) D.M. Water Addition Record

Sr. No.	Date	Time	Stage	Added DM Water in Ltr	Done By	Checked By

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F. MANUFACTURING RECORD

3) PREFILTRATION UNIT **DATE:_____**

Time	Temp (˚C)	Inlet pressure (Bar)	Outlet pressure (Bar)	Flow Rate (Lit/hr)	Vol. (Lit.)	Permeate pressure 1	Permeate pressure 2	Permeate pressure 3	Sign of Chemist

Sign of Chemist

Reviewed By -	Approved By -

F. MANUFACTURING RECORD

4) ULTRAFILTRATION STAGE - 1 **DATE : _____**

Time	Temp (˚C)	Pump Speed (RMP)	Pump Outlet pressure (A001)	Feed Pressure A002	Retentate Pressure A004	Permeate pressure A101	Permeate Flow rate (Ltr./Hrs.)	Sign

F. MANUFACTURING RECORD

5) **ULTRAFILTRATION STAGE - 2** **DATE : _____**

Time	Temp (˚C)	Pump Speed (RMP)	Pump Outlet pressure (A001)	Feed Pressure A002	Retentate Pressure A004	Permeate pressure A101	Permeate Flow rate (Ltr./Hrs.)	Sign

Sign of Chemist

Reviewed By -

Approved By -

H. BATCH RECONISILIATION

01.	Qty. of Whey Received. (A)	:		Lts
02.	Qty. of Whey Consumed (B)	:		Lts
03.	Qty of Water added as Di filtration (C)	:		Lts
04.	Qty. of Preservatives solution added (D)	:		Lts
05.	Qty. of Citric Acid solution added (E)	:		Lts
06.	Theoretical B.Size ≡ Qty. of Whey Received (A)	:		Lts
07.	Theoretical Qty. obtained after process (F) = (B+C+D+E)	:		Lts
08.	Actual Qty. obtained after process. (G)	:		Lts
09.	Mfg. Loss = F-G	:		Lts
10.	Yield Obtained	:		%

Sign of Chemist

Reviewed By -

Approved By -

I. RELEASE OF BATCH

ANALYTICAL CONTROL DATA FOR BULK SAMPLE		
Test	**Standard**	**Observation**
Description		
PH		
Fat		
Protein		
SNF		
Lactose		

MICROBIOLOGICAL CONTROL DATA FOR BULK SAMPLE		
Test	**Standard**	**Observation**
S.P.C.		
Y & M		
Coli Form		
Salmonella		
Listeria		
S.Aureus		

A . RELEASE OF BATCH FOR PACKAGING

A.R. No. _____
Date.: _____

_____
Q.A.OFFICER:

B. VERIFICATION

Batch Records Verified: _____ _____

PRODUCTION MANEGER **QA MANEGER**

Sign of Chemist

Reviewed By -

Approved By -